

Understanding Inflammation, Infection and Interventions in Severe Exacerbations of Cystic Fibrosis

NCT07484607

Status	RECRUITING
Sponsor	Alexander Horsley
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (9)

- Confirmed diagnosis of cystic fibrosis (CF), defined as presence of two pathogenic CF-causing CFTR mutations AND clinical features consistent with a diagnosis of CF, OR presence of at least one pathogenic CF-causing CFTR mutation AND sweat chloride (before use of CFTR modulators) $>60\text{mmol/L}$ AND clinical features consistent with a diagnosis of CF.
 - Receiving care from a UK Adult Cystic Fibrosis Centre taking part in the study.
 - EITHER:
 - Have had at least 1 previous exacerbation of CF lung disease, treated with intravenous antibiotics, in the previous 12 months.
 - OR
- ... and 4 more (see full listing online)

Exclusion (9)

- When attending for the baseline visit participants should be clinically stable at the time of the visit. This is defined as no acute change in their baseline symptoms or presence of new viral symptoms. They should not be on additional antibiotics or anti-viral therapies for any reason (above their usual medications), and should have completed any such additional therapies at least 4 weeks prior.
 - Extensive antibiotic allergies or intolerances that mean they could not be treated with standard CF antibiotic regimens, as outlined in section 5.6.
 - Subjects with infection with Mycobacteria tuberculosis
 - Subjects with active ABPA, defined as receiving treatment for ABPA currently or within the last 4 months, or those considered at risk of requiring treatment for ABPA in the next 12 months.
 - Subjects receiving long term oral steroids at an equivalent dose of 10mg or more per day of prednisolone.
- ... and 4 more (see full listing online)

Locations (6 total)

Cardiff and Vale University Health Board, Cardiff, United Kingdom
Royal Devon and Exeter Hospital (Wonford), Exeter, United Kingdom
Leeds Adult CF Centre, Leeds, United Kingdom
... and 3 more locations